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REMARKS

I. Status of Claims

Claims 1, 3-9, 12-22, 24-25, and 27 are currently pending in the application. Claims 2, 10, 23, and 26 are canceled without prejudice to the subject matter therein. Claim 11 was previously canceled. Claims 1, 7-9, 15-16, 21-22, and 27 are amended herein. Claims 1, 8, 15, and 21 are independent.

Claims 15-20 are allegedly withdrawn for containing subject matter not described in the elected species. Claim 26, which is withdrawn by the office action, is also rejected under the contention that it introduces new matter. Claims 10 and 21-25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Each pending claim also stands rejected under Section 102 and/or Section 103 of the Patent Act. Claims 1-3, 7-10, 14, 21-23, and 27 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,616,626 to Crank et al. Claims 1, 3, 6, 8, 10, 14, 21, and 23 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 6,045,565 to Ellis et al. Claims 4, 6, 12, 13, and 24-25 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Crank '626/Ellis '565 in view of U.S. Patent No. 5,758,663 to Wilk et al. Claims 5-6 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ellis '565 in view of U.S. Patent No. 6,964,649 to Goll.

II. Request for Withdrawal of Finality Under MPEP § 706.07

Prior to addressing the substance of the Office Action, Applicant respectfully requests withdrawal of the finality of the March 31, 2006, final Office Action. Given the requirement of section 706.07 of the MPEP that an applicant is entitled to a full hearing and that issues between the applicant and examiner should be developed <u>before</u> an appeal, withdrawal of the finality of the rejection is in order. As shown below, several times the Office Action relies upon references that do not qualify as prior art because the cited references are patents "commonly owned" by the Applicant. Indeed when the common ownership is foreseeable, the MPEP at section 706.07a specifically provides that "[w]hen applying any 35 U.S.C. 102(e)/103 references against the claims of an application the examiner should anticipate a statement averring common ownership at the time the invention was made to disqualify any patent or patent application applied in a rejection under 35 U.S.C. 103 based on 35 U.S.C. 102(e)."

As is the case here with claim 5, when the disqualified reference is the sole basis of rejecting a claim, the deputy commissioner has interpreted the rules to require the withdrawal of the finality of the rejection. Deputy Commissioner Kunin, in the Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, or an Obligation of Assignment to the Same Person, as Required by 35 U.S.C. 103(c), discussed:

If a final rejection of certain claims is obviated by a timely reply based on a proper claim of entitlement to the new exclusion, then the Office should acknowledge the reply by modifying the status of the claims. For example, if the only rejection in the final rejection is obviated by evidence demonstrating entitlement to exclude prior art under amended 35 USC 103(c) in the reply, the Office should indicate that the claims are allowable, or prosecution should be reopened should the claims be considered unpatentable in view of newly applied prior art. Applicant's evidence concerning the exclusion are entitled to being considered even after a final rejection has been made, since if the exclusion is established, the propriety of the rejection is obviated as a matter of law.

See 1241 USPTO O.G. 96 (December 26, 2000). (emphasis added)

Now, predicated on the following representations of common ownership withdrawal of the finality of the office action is requested.

Application 10/078,676 and U.S. Patent No. 6,616,626 were, at the time the invention of Application 10/078,676 was made, commonly owned by SciMed Life Systems, Inc.

Application 10/078,676 and U.S. Patent No. 6,964,649 to Goll were, at the time the invention of Application 10/078,676 was made, commonly owned by SciMed Life Systems.

Please note that Application 10/078,676 lists SciMed Life Systems as the assignee and Goll '649 lists Boston Scientific SciMed, Inc. as the assignee. Both were commonly owned by SciMed Life Systems, Inc. at the time the '676 invention was made, however, the name of SciMed Life Systems, Inc. was subsequently changed. A paper was filed in the USPTO on 12/22/04 that changed SciMed Life Systems, Inc. to Boston Scientific SciMed, Inc. See Reel/Frame: 016448/0940.

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III. Election/Restrictions

Applicant respectfully traverses the Examiner's withdrawal of claims 15-20. In the August 19, 2005 Office Action the Examiner indicated that claims 1, 8, 15, and 21 were generic to a plurality of species, specifically, figures 1-3, 5-6, and 8. Accordingly, in response to this action, the Applicant elected figures 5-6 for prosecution. All of the limitations in claims 15-20, as amended, are supported by figures 5-6 and described in detail in the specification. In the previous response, the Applicant changed therapeutic material to plug forming material. There is support for this amendment in paragraph [0042] of the as-filed specification, which when describing figures 5-6 states, "...a plug forming matrix, compound, or material may be injected from the first channel." See Figure 5, reference numeral 514.

Claims 15-20, as amended, are supported by elected figures 5-6 and are consistent with the subject matter the Applicant initially elected and which the Examiner has previously acted on the merits. Therefore, it is improper to withdraw claims 15-20 from consideration – no undue burden can arise from claims that have already been entered, reviewed at least twice and examined.

IV. 35 U.S.C § 112 2nd paragraph

The claims are amended to correct any perceived ambiguity.

Also, Applicants submit that claim 26 is fully supported by the as-filed specification, which shows the pressure apron being slidable off of the catheter in at least figures 1 and 4a. Nevertheless, claim 26 is canceled to streamline prosecution.

V. Rejection of Independent Claims 1, 8, 15, 21

a. <u>Crank '626</u>

Claims 1-3, 7-10, 14, 21-23, and 27 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,616,626 to Crank et al.

Applicants respectfully assert that the claims are patentably distinct over Crank '626 because it does not disclose or suggest at least the following claim language:

Claim 1: "...the <u>first and second channels in fluid communication with a plug</u> forming material." (emphasis added)

Claim 8: "...a catheter with a lumen and <u>a catheter piercing tip</u>" (emphasis added)

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Claim 15: "...a plug forming material ... a pressure apron slidably coupled to the catheter..."

Claim 21: "...a catheter with a lumen and a pressure apron surrounding the lumen, the pressure apron slidable on the catheter"

As illustrated in figures 10-12b of Crank '626, Crank '626 has an outer tube 408, a distal flange 410, a first lumen 416, and a second lumen 418. The first lumen 416 is used to inject radiopaque material, while a second lumen 418 is used to inject a drug as part of a PMR procedure. Crank '626 does not, however, disclose two channels in fluid communication with a drug or a plug forming material. Crank '626 also does not disclose an outer tube 408 having a piercing tip nor are the outer tube 408 and the distal flange 410 slidably coupled. Rather, the outer tube of Crank '626 terminates into distal flange 410 and the two components are unitary. Thus, lacking any discussion and/or suggestion of such an injection device, catheter, and plug forming material, Crank '626 fails to disclose at least the cited language of claims 1, 8, 15, and 21.

For at least these reasons, claims 1, 8, 15, and 21 and their dependents claims are patentable over Crank '626.

b. Ellis '565

Claims 1, 3, 6, 8, 10, 14, 21, and 23 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 6,045,565 to Ellis et al.

Applicants respectfully assert that the claims are patentably distinct over Ellis '565 because Ellis '565 does not disclose or suggest at least the following claim language:

Claim 1: "...the first and second channels in fluid communication with a plug forming material." (emphasis added)

Claim 8: "...a catheter with a lumen and <u>a catheter piercing tip</u>" (emphasis added)

Claim 15: "...a plug forming material ... a pressure apron slidably coupled to the catheter"

Claim 21: "...a catheter with a lumen and a pressure apron surrounding the lumen, the pressure apron slidable on the catheter."

Rather, as illustrated in figures 7-9 of Ellis '565, Ellis '565 discloses an injection catheter having an injection tube 190 with a piercing tip 127 and a hood 163. There is no discussion of a plug forming material nor a second channel within Ellis '565. Further, there is no discussion or

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suggestion of a catheter having a piercing tip or a catheter slidably placed on the hood. Lacking any discussion and/or suggestion of such a plug forming material or catheter, Ellis '565 fails to disclose or suggest the cited language of claims 1, 8, 15, and 21.

For at least these reasons, claims 1, 8, 15, and 21 and their dependent claims are patentable over Ellis '565.

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VI. Conclusion

In view of the above amendments and remarks, it is believed that the above-identified application is in condition for allowance, and notice to that effect is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

The Commissioner is authorized to charge any fees or credit any overpayments which may be incurred in connection with this paper under 37 C.F.R. §§ 1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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